Advanced Dental Solutions Ltd.
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APR 2 0 2012

510(k) SUMMARY

510(k) Number K 112795

5.1 Applicants Name: Paltop Advanced Dental Solutions Ltd.
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5.2 Contact Person: Tal Hammer-Topaz
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5.3 Date Prepared: August 2011

5.4 Trade Name: Paltop Advanced Dental Solution System

5.5 Classification Name: Implant, Endosseous, Root-form

5.6 Common usual name: Dental Implant

5.7 Medical Specialty: Dental

5.8 Product Code: DZE, NHA

5.9 Device Class: Class II

5.10 Regulation Number: 872.3640

5.11 Review Panel: Dental Device Panel

5.12 Predicate Devices:

- Alpha-Bio Tec® Dental Implant System (Alpha Bio Tec Ltd.) cleared under K063364; product code DZE (Implant, Endosseous, Root-form).
- MIS Dental Implant System (MIS – Implant Technologies Ltd.) cleared under K040807; product code DZE (Implant, Endosseous, Root-form).

- Osseospeed TM Profile System (ASTRA Tech AB) cleared under K080156, K091239) ; product code DZE (Implant, Endosseous, Root-Form)
- ARSD Dental Implants (ARDS Ltd.) cleared under K071803 ;product code DZE (Implant, Endosseous, Root-Form)
- NobleActive internal Connection Implant (Nobel Biocare AB) cleared under K071370; product code DZE (Implant, Endosseous, Root-Form); product code NHA (Abutment, Implant, Dental, Endosseous).

5.13 Intended Use / Indication for Use:

The Paltop Advanced Dental Solutions Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Paltop Dental Advanced Dental Implant Solutions System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

5.14 Device Description:

Paltop Advanced Dental Solutions Implant System consists of a one and two stage endosseous screw type implant with internal hexagonal connection, intended for single use. Each implant is accompanied by standard cover screws, healing caps, abutment system superstructures and surgical instruments.

The Paltop dental implant system is composed of the following implant families: Paltop ***Advanced*** screw type implants and Paltop ***Dynamic*** screw type implants. Each implant is accompanied by a standard cover screw. Paltop dental implants are made of Ti 6Al 4V ELI, and shall meet the requirements of ASTM F136.

"Paltop Advanced" are screw type implants, with double leaded "V" shape progressive external thread profile along the implants body, and fine threads at its neck. It has an internal hex. connection and a domed apex. The implant is available in 3.75mm, 4.2mm and 5mm diameter and lengths of 8mm, 10mm, 11.5mm, 13mm and 16mm (as detailed in Table 2: System Components). The implants are suitable

for both one and two stage implant procedures.

"Paltop Dynamic" are screw type implants, with 3 different thread geometries: double leaded "V" shape progressive external thread profile at the apical portion, modified reverse buttress along its body and fine thread at the neck. It has an internal hex. connection. The implant is available in 3.75mm, 4.2mm and 5mm diameter and lengths of 8mm, 10mm, 11.5mm, 13mm and 16mm (as detailed in Table 2: System Components). The implants are suitable for both one and two stage implant procedures.

The Paltop Advanced Dental Implant System includes a variety of abutments having a central bore and a lower mating surface that is configured to mate with the mating surface of the Paltop implant.

A collar portion is located at a coronal end of the dental implant. A central bore extends through the collar portion and into the implant body portion. The central bore includes a threaded section for receiving a threaded portion of a screw and post receiving section. The post receiving section consists of hex geometry for anti-rotational features and a conical section (above the hex) which interfaces with the abutment. The designed threads provides secure primary fixation. This design is responsible for transferring the load from the abutment/prosthesis to the implant body.

5.14 Substantial Equivalence:

The proposed Paltop Advanced Dental Solutions Implant System has similar indications for use, technological characteristics, mode of operation and performance specification as the predicates Alpha-Bio Tec® Dental Implant System (K063364), MIS Dental Implant System (K040807), ARSD Dental Implants (K071803), Osseospeed™ Profile System (K080156, K091239) and NobleActive internal Connection Implant (K071370).

The proposed device has the same intended use as the predicate Alpha-Bio Tec® Dental Implant System and MIS Dental Implant System and is placed using the same methodology as the predicate devices. Both the proposed and predicate devices function in the same manner providing support for prosthetic devices in the upper or lower jaw.

Technological Characteristics – comparative table

	Paltop Implant System	Alpha-Bio Tec® Dental Implant System	MIS Dental Implant System
K#		Cleared under K#063364	Cleared under K#040807
Product Code	DZE	DZE	DZE
Manufacturer	Paltop Advanced Dental Solutions Ltd.	Alpha-Bio Tec Ltd.	MIS Implant Technologies Ltd.
Intended Use/ Indications for Use	The Paltop Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Paltop Dental Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The Alpha-Bio Dental Implant System® is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Alpha-Bio Dental Implant System®Is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The MIS Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.
Limitations on Indications/Contraindications/ Relative Contraindications	Serious internal medical problems, bone metabolism disturbances, uncontrolled bleeding disorders, inadequate wound healing capacity, poor oral hygiene, maxillary and mandibular growth not completed, poor general state of health, uncooperative, unmotivated patient, drug or alcohol abuse, psychoses, prolonged therapy-resistant functional disorders, xerostomia, weakened immune system, illnesses requiring periodic use of steroids, titanium allergy, uncontrollable endocrine disorders. Relative contraindications: Previously irradiated bone, diabetes mellitus,	Patients who take steroid based, anticonvulsant and anticoagulant drugs. Patients receiving radiotherapy, chmotherapy or any other immunosuppressive treatment or who have been administered radiotherapy in the past 5 years. Metabolic bone disorders, uncontrolled bleeding disorders such as: hemophilia, thrombocytopenia, granulocytopenia. Degenerative diseases, osteoradionecrosis, renal failure, organ transplant recipients, AIDS, malignant diseases, diseases that compromise the immune system, unbalanced diabetes mellitus, psychotic diseases, hypersensitivity to one of the components of the implant ingeneral and titanium in particular, pregnancy, inability of the patient to maintain reasonable oral hygeine, lack of patient cooperation, use of alcohol, narcotics and uncontrolled endocrine disease. Any systemic condition that is unbalanced	The contraindications customary in oral surgery with other implant materials should be observed. These include patiens on corticosteroids, anticoagulants or anticonvulsant and those receiving radiation or other immunosupressive therapy. Lactating or pregnant woman are not candidates, nor are patients with abnormal laboratory values for BUN, creatinine or serum calcium. Patients with diabetes or cardiovascular disease are contraindicated. Hypertension above 110/170mmHG, osteoportic crush fractures, respiratory disease, thyroid or parathyroid disease should be excluded from treatment. Patients with diagnosed malignancy in the past five years and those with nodular enlargements, tenderness or unexplained lumps or masses of the head or neck should not be treated. Implanting procedures should not be performed on persons with active osteolitic, inflammatory or infectious

	anticoagulation drugs/hemorrhagic diatheses, bruxism, parafunctional habits, unfavorable anatomic bone conditions, tobacco abuse, uncontrolled periodontitis, temporomandibular joint disorders, treatable pathologic diseases of the jaw and changes in the oral mucosa, pregnancy, inadequate oral hygiene	and therefore precludes surgical procedures. Relative contraindications: Previously irradiated bone, treatment with anticoagulant drugs or bisphosphonates, bruxism, parafunctional habits, untreated and/or uncontrolled periodontal disease; temporomandibular joint disease, varous pathologies of the oral mucosa.	processed in the implantation site. The folloiwng outline lists the contraindications: Debilitating or uncontrolled disease; pregnance, hemophilia; granulocytopenia or other bleeding problems, steroid use, prophylactic antibiotics, britlle diabetes, Ehler-Danlos syndrome; osteoradionecrosis, renal failure, organ transplanation anticoagulation therapy; unexplained hypersensitivity, fibrous dysplasis, regional enteritis.
User Population	Adult and young patients who have been screened to ascertain that there is sufficient alveolar bone width to support the implant. In general anyone healthy enough to undergo routine tooth extraction or oral surgery is probably able to receive an implant.	Adult and young patients who have been screened to ascertain that there is sufficient alveolar bone width to support the implant. In general anyone healthy enough to undergo routine tooth extraction or oral surgery is probably able to receive an implant.	Adult and young patients who have been screened to ascertain that there is sufficient alveolar bone width to support the implant. In general anyone healthy enough to undergo routine tooth extraction or oral surgery is probably able to receive an implant.
Components	The Paltop Advanced Dental Solutions Implant System consists of one and two stage endosseous form dental implants, internal hexagonal connection; cover screws and healing caps; abutment systems and superstructures; surgical instruments.	The Alpha-Bio Dental Implant System® consists of one and two stage endosseous form dental implants, internal and external hexagonal; internal octagonal hexagonal; one piece implants system; cover screws and healing caps; abutment systems and superstructures; surgical instruments.	The MIS Dental Implant System consists of one and two stage implants, internal and external hexagonal; cover screw and healing caps; abutment systems and suprastructures; surgical instruments.
Accessories	Surgical Instruments	Surgical Instruments	Surgical Instruments
Intended Use Environment	Dental Clinic Setting	Dental Clinic Setting	Dental Clinic Setting
Clinical Data	N/A	No information was provided in the 510K notice.	No information was provided in the 510K notice.
Standards with which the Device Complies	1. FDA Guidance - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments. 2. ISO 14801:2007 "Dentistry-Implants- Dynamic fatigue test for endosseous dental implants". 3. ISO 5832-3:1996 - Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy. 4. ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-	ISO 7405:1997, Dentistry- Preclinical Evaluation of Biocompatibility of Medical Devices Used in Dentistry - Test Methods for Dental F136-02a: 2004 Standard Specification for Wrought Titanium-6Alumnlnum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401). ASTM F1350-02, 2002 Standard Specification for Wrought 18 Chromium-14Nickel-2.5 Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673). ISO 13402:1995, Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion and thermal exposure.	ASTM F67-95 ISO 9001:2000 ISO 13485:2003

	4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications. 5. ASTM F899 Standard Specification for Wrought Stainless Steels for Surgical Instruments. 6. ASTM F746-04 (Reapproved 2009) - Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials. 7. ISO 10993-1:2003 Biological evaluation of medical devices - Part 1: Evaluation and testing. 8. ISO 14971:2007 - Risk Analysis for Medical Device. 9. ISO 9001:2008 - Quality management systems requirements. 10. ISO 13485:2003 (including CMDCAS Medical Device Regulations) - Quality systems medical devices. 11. ISO 11137:2006 Sterilization of health care products – Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices. 12. ISO 11607: Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems. 13. ISO 15223:2000: Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied.	UL 544 (1998):, Standard for Medical and Dental Equipment - Ed. 4.0.	
Technological Characteristics	• Material composition: Titanium alloy • Surface treatment: Sandblasting "aluminum oxide particles" and Acid Etching HCl & H_2SO_4 • Dimensions/angulations 1. Implants: Diameter 3.75mm, 4.2mm, 5mm Lengths: 8, 10, 11.5, 13, 16m 2. Abutments 15° - 25°,	• Material composition: Titanium Alloy • Surface treatment: Sandblasting "aluminum oxide particles" and Acid Etching HCl & H_2SO_4 • Dimensions/angulations 1. Implants: Diameter: 3.75 – 6mm, Lengths: 8, 10, 11.5, 13, 16mm 2. Abutments 15° - 25°, Diameter 3.9 - 4.5mm, Lengths: gum height 1-4mm • Internal hex connection	• Material composition: Titanium Alloy • Surface treatment: Sandblasting "aluminum oxide particles" and Acid Etching HCl & H_2SO_4 • Dimensions/angulations 1. Implants: Diameter: 3.25-6mm, Lengths: Diameter 3.3: 10,11.5, 13, 16mm Diameter 3.75: 8, 10,11.5, 13, 16mm Diameter 4.2: 6, 8, 10,11.5, 13, 16mm

	Diameter 4-5.5mm, Lengths: gum height 1-3mm • Internal Hex Connection		Diameter 5 & 6: 6, 8, 10,11.5, 13, 16mm 2. Abutments: 15° - 25°, Diameter 4-5.5mm, Lengths: gum height 1-4mm • Internal hex connection

The Paltop Dental Implant System has the following similarities to predicate devices:

- Has the same intended use
- Uses the same operating principle
- Incorporates the same basic design
- Incorporates the same materials
- Has similar packaging
- Is sterilized using the same procedures

Non Clinical Tests:

A series of safety and performance testing were performed to demonstrate that the Paltop Advanced Dental Solutions Implant System does not raise any new issues of safety and efficacy. These tests include: fatigue, corrosion resistance, surface analysis and biocompatibility.

The device complies with the following standards:

1. FDA Guidance – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments.
2. ISO 14801:2007 "Dentistry Implants Dynamic fatigue test for endosseous dental implants".
3. ISO 5832-3:1996 Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.
4. ASTM F136 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications.
5. ASTM F899 Standard Specification for Wrought Stainless Steels for Surgical Instruments
6. ISO 7405:2008 Dentistry -- Evaluation of biocompatibility of medical devices used in dentistry.
7. ASTM F746 - 04(2009) Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials.

8. ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.

All these tests demonstrate that the Paltop Advanced Dental Solutions Implant System is substantially equivalent to its predicates without raising new issues of safety or effectiveness.

Clinical Tests

A clinical evaluation has been performed based on a literature review.

From current knowledge this literature evaluation of the Paltop Dental Implant System provides sufficient evidence:

- The presented studies demonstrate that titanium-based dental implants can be installed safely in human patients with a very high overall success rate.
- The present studies demonstrate compliance of the device in question with the essential requirements (in particular regarding safety and performance) under normal conditions of use.
- That the device performs as intended by the manufacturer;
- That the device does not pose any undue safety concerns to either the recipient or end-user.
- That any risks associated with the use of the device are acceptable when weighed against the benefits to the patient.

Summary:

Based on performance testing results, and compliance to performance standards Paltop Advanced Dental Solutions Ltd. believes that the Implant System is substantially equivalent to its predicates without raising new issues of safety or effect

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Tal Hammer-Topaz
Quality, Regulatory & Clinical Manager
Paltop Advanced Dental Solutions Ltd.
5 Hashita Street
Caesarea
ISRAEL 30889

APR 2 0 2012

Re: K112795
Trade/Device Name: Paltop Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: March 28, 2012
Received: April 9, 2012

Dear Ms. Hammer-Topaz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112795

Device Name: PALTOP Advanced Dental Solutions System

Indications for Use:

The Paltop Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Paltop Dental Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Prescription Use __√_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices